Preliminary Amendment Serial No. (PCT/GB2004/003329)

Filed: (30 July 2004)

## **IN THE CLAIMS**:

1. (Currently Amended) An oral drug delivery system which comprises a biliquid foam comprising:

from 1 to 20% by weight of a continuous hydrophilic phase,

from 70 to 98% by weight of a pharmaceutically acceptable oil which forms a discontinuous phase, the said pharmaceutically acceptable oil having dissolved or dispersed therein a poorly water-soluble drug in an amount of from 0.1 to 20% by weight, said poorly water-soluble drug dissolving in water in an amount of less than 1% by weight, and the biliquid foam including therein from 0.5 to 10% by weight of a surfactant to enable the formation of a stable biliquid foam, all percentages being based upon the total weight of the formulation.

- 2. (Original) An oral drug delivery system as claimed in claim 1 wherein the continuous hydrophilic phase is an aqueous phase.
- 3. (Original) An oral drug delivery system as claimed in claim 2 wherein the aqueous phase is water.
- 4. (Original) An oral drug delivery system as claimed in claim 2 wherein the aqueous phase incorporates a salt or a co-solvent therein.
- 5. (Original) An oral drug delivery system as claimed in claim 1 wherein the continuous hydrophilic phase is a non-aqueous solvent.
- 6. (Original) An oral drug delivery system as claimed in claim 5 wherein the non-aqueous solvent is an aliphatic alcohol, polyethylene glycol, propylene glycol or glycerol, or mixtures thereof.

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7. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the pharmaceutically acceptable oil is a mono-, di- or triglyceride, or a mixture thereof.

- 8. (Original) An oral drug delivery system as claimed in claim 7 wherein the mono-, di- or triglycerides are the glycerol esters of fatty acids containing from 6 to 22 carbon atoms.
- 9. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the surfactant comprises an alkyl polyglycol ether, an alkyl polyglycol ester, an ethoxylated alcohol, a polyoxyethylene sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a polyoxyethylene fatty acid ester, an ionic or non-ionic surfactant, a hydrogenated caster oil/polyoxyethylene glycol adduct containing from 25 to 60 ethoxy groups, a castor oil/polyoxyethylene glycol adduct containing from 25 to 45 ethoxy groups, or mixtures thereof.
- 10. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 which includes therein a coemulsifier in an amount sufficient to complete the solubilization of the poorly water-soluble drug.
- 11. (Original) An oral drug delivery system as claimed in claim 10 wherein the co-emulsifier is a phosphoglyceride or a phospholipid.
- 12. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the discontinuous phase comprises from 85 to 96% by weight of the biliquid foam.

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13. (Original) An oral drug delivery system as claimed in claim 12 wherein the discontinuous phase comprises from 90 to 95% by weight of the biliquid foam.

- 14. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the continuous hydrophilic phase comprises from 2 to 10% by weight of the biliquid foam.
- 15. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the surfactant comprises from 0.5 to 5% by weight of the composition.
- 16. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the poorly water-soluble drug is an analgesic or anti-inflammatory agent, an anthelmintic, an anti-arrhythmic agent, an anti-coagulant, an anti-depressant, an anti-diabetic, an anti-epileptic, an anti-fungal agent, an anti-gout agent, an anti-hypertension agent, an anti-malarial, an anti-migraine agent, an anti-muscarinic agent, an anti-neoplastic agent, an anti-protozoal agent, an anti-thyroid agent, an anxiolytic, sedative, hypnotic or neuroleptic agent, a corticosteroid, a dieuretic, an anti-Parkinsonian agent, a gastro-intestinal agent, a histamine H-receptor antagonist, a lipid regulating agent, an anti-anginal agent, a nutritional agent, an opiod analgesic, a sex hormone, a stimulant, or a therapeutic mixture thereof.

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17. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 which is in a unit dosage form.

18. (Original) An oral drug delivery system as claimed in claim 17 wherein the unit dosage form comprises capsules filled with the biliquid

foam.

19. (Original) An oral drug delivery system as claimed in claim 18

wherein the capsules are hard or soft gelatin capsules.

20. (Currently Amended) An oral drug delivery system as claimed in

any one of claims 1 to 16 claim 1 which is in the form of a dilutable

concentrate.

21. (Original) An oral drug delivery system as claimed in claim 20

which is infinitely dilutable in a co-solvent.

22. (Currently Amended) An oral drug delivery system as claimed in

any one of the preceding claims claim 1 for use in a method of treatment

by oral administration to the human or animal body.

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